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09/988,850	11/19/2001	John F. Gordon	111465-128	7587

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EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,850

Applicant(s)

GORDON ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1, drawn to a method for determining a blood group type of an individual by direct typing on a bio-disc, classified in class 436, subclass 521.
- II. Claims 2 and 4, drawn to a method for determining the presence of antibodies to a blood group type, classified in class 435, subclass 7.25.
- III. Claims 3 and 5, drawn to a method for determining the presence of antibodies to a blood group type by reverse typing on an optical bio-disc, classified in class 435, subclass 7.2.
- IV. Claim 6, drawn to an apparatus for determining a blood group type of an individual, classified in class 73, subclass 54.28.
- V. Claim 7, drawn to an optical bio-disc for performing a bloody-typing assay, classified in class 422, subclass 68.1.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I, II and III are unrelated, independent and distinct inventions.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I is a method for determining a blood group type of an individual by direct typing, requiring the application of red blood cells to at least one chamber of an optical bio-disc, which invention II does not, and placing the disc

Art Unit: 1641

into an optical reader that supports it on a first side, which invention III does not.

Invention II requires the purification of serum, which inventions I and III do not.

Invention III requires the spinning of the bio-disc at different speeds and in different directions, which inventions I and II do not. Therefore, these inventions are independent and distinct.

2. Inventions I, II, III and IV, V are related as process and apparatus for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the inventions of IV and V can be used as centrifuges.

3. Inventions IV and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination as claimed does not appear to require the features found in the subcombination. The subcombination has separate utility such as a portable centrifuge or as a means for storing data.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for others, restriction for examination purposes as indicated is proper.

Art Unit: 1641

5. During a telephone conversation with Donald Bollella on August 8, 2003 a provisional election was made with traverse to prosecute the invention of group V, claim 7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-6 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

6. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide

Art Unit: 1641

adequate support under 35 U.S.C. 112 for claim 7 of this application. There does not appear to be any support in the provisional applications for the design of the optical bio-disc as recited in claim 7.

Information Disclosure Statement

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

8. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

Art Unit: 1641

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

9. The abstract of the disclosure is objected to because in line 2 of the abstract, the phrase "a methods" is ambiguous. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the last line, "a capture zone" is confusing in that it fails to indicate or distinguish whether the capture zone is the same as the capture zone in the first detection chamber, or if it is entirely separate from the first capture zone.

12. The term "associated with" in claim 7 is a relative term which renders the claim indefinite. The term "associated with" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what

Art Unit: 1641

would be encompassed by the term “associated with”, whether to indicate physical connectivity, or to indicate some form of wireless communication.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al [US 5,922,591]. The limitations of the system as currently recited in claim 7 are broad enough to read upon the system taught by Anderson, requiring specifically a substrate, a separation chamber with a means of filtering, a first and second mixing chamber with inlet ports, and a first and second detection chambers.

Anderson teaches an apparatus comprising a substrate (column 2, lines 24-26), a separation chamber with a filter means associated with the separation chamber (column 2, lines 45-49, 64-67), a first and second mixing chamber (hybridization, reaction chambers) with inlet ports (column 2, lines 20-39, 54-60, column 21, lines 22-24), and a first (analytical chamber with a oligonucleotide array) and second (microcapillary eletrophoresis device) detection chamber (column 24, lines 5-20).

Claim Rejections - 35 USC § 103

Art Unit: 1641

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen [US 6,030,581] in view of Burd [US 5,061,381]. Virtanen discloses an optical disk having a substantially self-contained assay means for localizing an analyte suspected of being in a sample to at least one, predetermined location. Specifically, Virtanen teaches an optical disk comprising a substrate, a separation chamber (analyte separation sector) including a first inlet port, a filter means associated with said separation chamber, a mixing chamber (sample preparation sectors) in fluid communication with said separation chamber, and a first detection chamber (assay site) in fluid communication with the first mixing chamber, as well as a second detection chamber (column 5, lines 28-53, column 6, lines 54-62, figures 1-4). Virtanen, however, does not teach that the feature of a second mixing chamber, with the second detection chamber being in fluid communication with the second mixing chamber. Instead, Virtanen teaches a second separation chamber, with the second detection chamber being in fluid communication with the second separation chamber (figure 2b). However, Burd teaches that it is "frequently desirable to divide the separated blood plasma into a plurality of discrete aliquots so that a variety of tests or assays may be performed on the blood. Such separation and division steps have heretofore been typically performed by centrifugation to separate the blood plasma from the cellular components" (column 1, lines 14-22). Burd further discloses that "multiple

Art Unit: 1641

metering chambers may be provided to allow combinations with different reagents or diluents in isolated separation chambers (column 11, lines 14-18). Therefore, it would be obvious to provide a second mixing chamber in fluid communication with the separation chamber and the second detection chamber in the method of Virtanen in order to allow combinations with different reagents or diluents in isolated separation chambers.

Conclusion

16. No claims are allowed.

17. The following references are also cited as art of interest: Burd [US 5,061,381], Virtanen [US 6,030, 581], Gordon [US 5,892,577], Hoshino et al [US 6,143,510], Gordon [US 6,339,473 B1], Zoval et al [US 2002/0163642 A1], Selvan [US 2003/0104486 A1], Kellogg et al [US 6,063,569], Kellogg et al [US 6,582,662 B1], Kellogg et al [US 2001/0001060 A1], Brotherston et al [US 6,399,361 B2], Katzman et al [US 5,750,074], Jewell [US 5,631,166], Klose et al [US 4,515,889], Amigo, L et al [*Rapid isolation of vesicular and micellar carriers of biliary lipids by ultracentrifucation*, 1990, Vol. 31, p.341-347].

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is 703-305-4508. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on 703-305-3399. The fax phone numbers for the

Art Unit: 1641

organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

NY



LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/19/03